UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Date: August 18, 1999

Subject: Acute toxicity data review for reregistration of OBPC product. Trade name: Sani-Glide

EPA Reg. No. 1677-128
DP Barcode: D242658
Case No. 2045

Sept 1, 1999

From: Hari Moy Mukhoty, DVM, PhD [Second review by : MJP]
Product Reregistration Branch (PRB)
Special Review and Reregistration Division (SRRD), Mail Code: 7508C

MJP

To: Veronica Dutch, CRM
PRB, SRRD, Mail Code: 7508C

Applicant: Ecolab Inc.
Ecolab Center
St. Paul, MN 55102

FORMULATION FROM EPA Reg. No. 1677-128 LABEL :

Active Ingredients:	% by wt.
o-benzyl-p-chlorophenol	1.50%
o-phenylphenol	1.50%
Inert ingredients	97.00%
Total :	100.0%

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on 100% Recycled Paper (40% Postconsumer)

BACKGROUND :

The Ecolab Inc. has submitted acute oral toxicity data to support the reregistration of their product EPA Reg. No. 1677-128. MRID No. for the acute oral toxicity study is: 443328-18.

As per the provisions of the OBPC RED, the data requirements for dermal and inhalation toxicities for this product are waived by placing each aforesaid route of exposure in Toxicity Category III. If the registrant is not willing to accept this classification, it will be needed to submit acceptable data for reregistration for this product.

This product is corrosive to skin & eyes. As per the provisions of 40CFR - 158.340, the primary eye and dermal irritation data requirement is waived by placing the product Toxicity Category I for these two routes of exposures.

The dermal sensitization data requirement is waived because this product has been placed into Toxicity Category I for dermal irritation (EPA Publication No. 737-R-97-002). However, the waiver is granted by placing it as a dermal sensitizer.

RECOMMENDATIONS:

The acute toxicity data requirements for reregistration of the undermentioned product are satisfied.

The acute toxicity profile for the product EPA Reg. No. 1677-128 is currently :

Acute oral toxicity	IV	Acceptable
Acute dermal toxicity	III	Waiver-acceptable
Acute inhalation toxicity	III	Waiver-acceptable
Primary eye irritation	I	Waiver-acceptable
Primary dermal irritation	I	Waiver-acceptable
Dermal sensitization	Sensitizer	Waiver-acceptable

LABELING:

ID # : 1677-128 SANI-GLIDE

RESTRICTED USE CLASSIFICATION RECOMMENDED:

Due to eye irritation, and dermal irritation toxicity categories :

The PM should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

SIGNAL WORD: DANGER PELIGRO

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

IF INHALED: Move the person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call poison control center or doctor for further treatment advice.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor.

Have the product container or label with you, when calling a poison control center or doctor or going for treatment

PRECAUTIONARY STATEMENT (HAZARDS TO HUMAN AND DOMESTIC ANIMALS) :

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed, or absorbed through the skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear, goggles or face shield and chemical resistant gloves (such as Barrier laminate, or Butyl/ Nitrile/Neoprene rubber, PVC, Viton with >/= 14 mils). Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

NOTE TO PHYSICIAN :

The following note to physician statement is required for the subject product:

Probable mucosal damage may contraindicate the use of gastric lavage.

NOTE TO PM/CRM/Registrant: "Note to Physician is needed to address Category I classifications".

The following statements are suggested types of information that may be included:

* technical information on symptomatology,
* use of supportive treatments to main life functions,
* medicine that will counter act the specific physiological effects of the pesticide,
* company telephone number to specific medical personnel who can provide specialized medical advice

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat
OPPTS 870.1100 [§81-1]

DP BARCODE: D242658
P.C. CODE: 064103, 062201

SUBMISSION CODE: S533212
TOX. CHEM. NO.:

TEST MATERIAL: SANI-GLIDE

SYNONYMS: O-PHENYLPHENOL

CITATION: Morris, T.D. (1997) Sani-Glide acute oral limit toxicity testing. Hill Top Research, Inc., Main and Mill Streets, Miamiville, OH 45147. Laboratory study number 97-8420-21, July 9, 1997. MRID 44332818. Unpublished.

SPONSOR: Ecolab, Inc. 840 Sibley Memorial Highway, Mendota Heights, MN 55118.

EXECUTIVE SUMMARY: In an acute oral LD_{50} study (MRID 44332818) five male and five female fasted young adult Sprague-Dawley rats were given a single oral 5000 mg/kg dose of undiluted SANI-GLIDE (Batch # ATG041401) by gavage and observed for 14 days.

There were no mortalities during the study. Observations for clinical signs revealed only slight hyopactivity on the day of dosing. All rats had normal body weight gains during the observation period following administration of the test material. There were no observable abnormalities at gross necropsy related to administration of Sani-Glide.

The oral LD_{50} for undiluted SANI-GLIDE was determined to be > 5000 mg/kg for male and female rats based on the results of this study.

This acute oral study is classified as **Acceptable** and does satisfy the guideline requirements for an acute oral study (§81-1) in the rat.

COMPLIANCE: Signed and dated GLP and Data Confidentiality statements were provided. A Quality Assurance statement was not provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: SANI-GLIDE

   Description: clear, amber liquid; soap odor
   Lot/Batch #: Batch # ATG041401
   Composition: not given

2. Vehicle and/or positive control

None

3. Test animals

Species: rat
Strain: Sprague-Dawley, albino
Age and/or weight at dosing: young adult; weight 222 - 283 g
Source: Harlan Sprague Dawley, Inc., Indianapolis IN
Acclimation period: 5 days
Diet: Teklad 4% mouse/rat diet, *ad libitum* except for overnight fast prior to dosing
Water: municipal water, *ad libitum*
Housing: groups of 5 in wire mesh suspension cages
Environmental conditions:
Temperature: 64 - 79 °F
Humidity: 30-70%
Air changes: not given
Photoperiod: 12 hour light/dark

B. STUDY DESIGN AND METHODS

1. In life dates

Start: May 13, 1997; End: May 27, 1997

2. Animal assignment and treatment

Animals were assigned to the test groups noted in Table 1. Following an overnight fast, five rats/sex/dose were given a single 5000 mg/kg dose of the undiluted test material. The animals were observed for clinical signs of toxicity and mortality frequently on the day of dosing and at least twice daily thereafter for 14 days. They were weighed prior to dosing, on study days 7 and 14, or at the time of discovery after death. All rats were sacrificed and necropsied.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg)	Males	Females	Combined
5000	0/5	0/5	0/10

Data taken from p. 15, MRID 44332818.

3. Statistics

Calculation of the oral LD_{50} was not necessary

II. RESULTS AND DISCUSSION

A. MORTALITY

There were no mortalities during the study.

The oral LD_{50} for undiluted SANI-GLIDE was determined to be > 5000 mg/kg for male and female rats based on the results of this study.

B. CLINICAL OBSERVATIONS

Observations for clinical signs of toxicity revealed only slight hypoactivity that was noted on the day of dosing. No other apparent signs of toxicity were noted throughout the remainder of the study.

C. BODY WEIGHT

All rats had normal body weight gains during the observation period following administration of the test material.

D. NECROPSY

There were no observable abnormalities at gross necropsy related to administration of Sani-Glide.

E. DEFICIENCIES

None.

ACUTE TOX ONE-LINERS :

1. **PC CODE :** 62201 and 64103

2. **Current Date:** August 18, 1999

3. **Test Material:** Sani-Glide, EPA Reg. No. 1677-128
   62201 o-benzyl-p-chlorophenol - 1.50%
   64103 o-Phenylphenol - 1.5%

Study/ Species/ Lab/ Study # / Date	MRID No.	Results	Tox. Cat	Core Grade
Acute oral toxicity	44332818		IV	A
Acute dermal toxicity	Waived*		III	A
Acute inhalation toxicity	Waived		III	A
Primary eye irritation	Waived**		I	A
Primary dermal irritation	Waived	.	I	A
Dermal sensitization	Waived***		-----	A

Core Grade Key: A=acceptable, U=unacceptable, S=supplementary (upgrade able), V=self-validated

* Waived studies required for 81-2, 81-3 vide provisions of OBPC RED.

** Waived data requirements for 81-4, and 81-5 because product pH is > 11.5 per MSDS No. 969048 dated August 29, 1996. (40 CFR-158-340)

*** Waived because dermal irritation is classified as Toxicity Category I.